

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In November, 2004, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Bassem Mikhail, M.D. Based on an echocardiogram dated April 22, 1999, Dr. Mikhail attested in Part II of Ms. Heddlesten's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the

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3. (...continued)

for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

range of 50% to 60%.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$567,341.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, Ronald Woodson, M.D., stated that Ms. Heddlesten had "[m]ild to moderate mitral valve insufficiency." Dr. Woodson, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In August, 2005, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for Dr. Mikhail's finding that claimant had moderate mitral regurgitation because claimant's echocardiogram demonstrated only mild mitral

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4. Dr. Mikhail also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

regurgitation. In support of this conclusion, Dr. Gradus-Pizlo explained that the "[r]egurgitation jet is visible mostly on the parasternal long axis view" and that "[i]t is minimal to mild [mitral regurgitation]. There are no jet area measurements on the tape likely because there is no [mitral regurgitant] jet visible on the 4 [chamber] view."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Heddlesten's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant argued that under the reasonable medical basis standard, the attesting physician's conclusions should be accepted unless they are "extreme or excessive." Claimant also asserted that Dr. Mikhail had a reasonable medical basis for his finding because it matched the finding of Dr. Woodson, who prepared the report for the echocardiogram on which the Green Form was based and who participated in the Trust's Screening Program.<sup>7</sup> Claimant further contended that "[q]uantifying the

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Heddlesten's claim.

7. See Settlement Agreement § IV.A.1. (Screening Program established under the Settlement Agreement). Under the  
(continued...)

level of regurgitation shown on an echocardiogram is inherently subjective."<sup>8</sup> Finally, claimant suggested that the Trust was not properly applying the reasonable medical basis standard established in the Settlement Agreement and that the auditing cardiologist simply substituted her own opinion for that of the attesting physician.<sup>9</sup>

The Trust then issued a final post-audit determination again denying Ms. Heddlesten's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Heddlesten's claim should be paid. On

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7. (...continued)

Settlement Agreement, the Gray Form was used to report the results of an echocardiogram performed in the Screening Program. See Settlement Agreement § VI.C.2.g. Notably, Dr. Woodson attested in claimant's Gray Form, based on a subsequent April 14, 2001 echocardiogram, that Ms. Heddlesten had mild mitral regurgitation.

8. In support of this argument, claimant submitted excerpts of depositions of five (5) physicians from other proceedings. None of the testimony submitted by claimant, however, addressed Ms. Heddlesten's echocardiogram.

9. Claimant also asserted that the Trust should ensure that its auditing cardiologists do not have any "biases" against claimants. As there is no evidence that the auditing cardiologist had a "bias," this issue is irrelevant for resolution of this claim. Similarly, claimant referenced, without any substantive discussion, a number of filings in MDL 1203. As claimant has not attempted to establish how those filings entitle her to Matrix Benefits, they are not pertinent to the disposition of this show cause claim.

March 20, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6077 (Mar. 20, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 2, 2006, and claimant submitted a sur-reply on June 23, 2006. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Heddlesten reasserts the arguments that she made in contest. In addition, without any support, claimant argues that there is a reasonable medical basis for the attesting physician's finding of moderate mitral

regurgitation because the auditing cardiologist agreed that Ms. Heddlesten had an abnormal left atrial dimension, which "can be caused by mitral regurgitation, [and] the degree of enlargement in this case supports the belief that Ms. Heddlesten has 'moderate' mitral regurgitation." Claimant also suggests that it is not uncommon for two cardiologists to review the same echocardiogram and to find different levels of regurgitation. According to claimant, "[n]either diagnosis is correct or incorrect; both fall within the realm of having 'a reasonable medical basis.'" Finally, claimant asserts that the Trust has "substituted the opinions of unbiased and well-qualified cardiologists with the opinions of auditing cardiologists that have been encouraged to deny claims over the slightest difference of subjective opinion."<sup>10</sup>

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard. Moreover, the Trust argues that claimant failed to rebut any of Dr. Gradus-Pizlo's specific findings.

In her sur-reply, claimant reasserts her argument that she should prevail because "echocardiogram interpretation is highly subjective." Claimant also notes that Dr. Woodson did not complete a Gray Form based on the April 22, 1999 echocardiogram

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10. In support of this argument, claimant refers to Dr. Gradus-Pizlo's conclusion in connection with another show cause claim. As the issue is whether Ms. Heddlesten has established a reasonable medical basis for her claim, claimant's reliance on the auditing cardiologist's conclusion regarding a different claimant is misplaced.

at issue, but rather a subsequent echocardiogram performed on April 14, 2001.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not adequately contest Dr. Gradus-Pizlo's finding of mild mitral regurgitation. Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Heddlesten rests only on Dr. Mikhail's check-the-box diagnosis on her Green Form and the report of the echocardiogram at issue in claimant's Green Form.<sup>11</sup> Claimant never identified any particular error in Dr. Gradus-Pizlo's conclusion. Mere disagreement with the auditing cardiologist without identifying and substantiating any specific errors by the auditing cardiologist is insufficient to meet a claimant's burden of proof.<sup>12</sup> On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

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11. In any event, this echocardiogram report does not establish a reasonable medical basis for Ms. Heddlesten's claim because it does not address Dr. Gradus-Pizlo's specific finding with regard to the echocardiogram. In particular, the April 22, 1999 echocardiogram report simply states that claimant had "[m]ild to moderate mitral valve insufficiency."

12. We also reject claimant's assertion that she should prevail simply because two cardiologists concluded that she had "at least 'mild to moderate' mitral regurgitation." Under the Settlement Agreement, claimant must establish that she has the requisite level of mitral regurgitation. As discussed herein, claimant has not met this burden.



We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Rules. The context of these two documents leads us to interpret the reasonable medical basis standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. Here, Dr. Gradus-Pizlo determined in audit, and Ms. Heddlesten does not adequately dispute, that the attesting physician's finding of moderate mitral regurgitation was unreasonable. Specifically, Dr. Gradus-Pizlo explained that the mitral regurgitation was "minimal to mild," and that "[t]here are no jet area measurements on the tape likely because there is no [mitral regurgitant] jet visible on the 4 [chamber] view."<sup>13</sup> Contrary to claimant's argument, Dr. Gradus-Pizlo properly applied the reasonable medical basis standard established under the Settlement Agreement.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of

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13. Similarly, we disagree with claimant that the conflict between the attesting physician and the auditing cardiologist is due to the "subjective nature of echocardiography." Nor has Dr. Gradus-Pizlo merely substituted her opinion for that of the attesting physician. Instead, Dr. Gradus-Pizlo specifically found that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Claimant, however, did not adequately refute or respond to this determination.

Ms. Heddlesten's claim for Matrix Benefits and the related derivative claim submitted by her spouse.